EXHIBIT A

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per email Jennifer.carver@cms.hhs.gov

Mauerbach, May 23, 2013

RE: May 29, 2013 HCPCS Public Meeting Agenda Item #6: P-STIM

Dear Ms. Hake:

I am writing to you regarding the application received by CMS for the creation of a HCPCS code for P-STIM™ that is currently Agenda Item #6 for the May 29th HCPCS Public Meeting. I apologize that I am writing to you so close in time to the public meeting; however, our company found out that a HCPCS code application was submitted in this application cycle only when the May 29th Public Meeting Agenda was posted and made public on approximately May 10th and it was brought to our attention by a third party. Recently Mr. Srini Nageshwar of the company DyAnsys, has identified himself to Biegler GmbH as the applicant on the HCPCS application, while we do not know whether that is the case as we have not seen the completed HCPCS application. Whether or not Mr. Nageshwar or a different person is the applicant on this HCPCS application, it is our opinion that the application submitted to establish a P-STIM code did not meet the process outlined in the HCPCS application form and the process documentation and is therefore invalid. We request that you formally withdraw this application from consideration immediately, delete Agenda item #6 currently planned for the May 29th HCPCS Public Meeting, and set aside the preliminary determination without prejudice so that the manufacturer may pursue a HCPCS code at a future date when it is prepared to do so.

REGULATORY STANDING OF BIEGLER GmbH

Biegler GmbH is the sole manufacturer of P-STIM devices for sale in the U.S. The FDA K-letter (K050123) dated January 17, 2005, refers to products with "Trade or Proprietary

Name: P-STIM". No other FDA K-letter refers to P-STIM. The product addressed by K-letter K050123 was previously distributed through NeuroScience Therapy Company which was then the U.S. distributor for Biegler GmbH. Since that time and continuing through the present, Biegler GmbH has remained the manufacturer of record for this K-letter and maintains the manufacturer file for the P-STIM product. No other manufacturer can identify regulatory standing to address products covered by letter K050123 besides Biegler GmbH. Any other manufacturer that indicates they are authorized to sign the "Manufacturer" signature line on page seven of the HCPCS application does not have standing to do so. Biegler GmbH welcomes the opportunity to provide documentation to this effect.

LACK OF INVOLVEMENT/ATTESTATION OF BIEGLER GmbH IN THE APPLICATION PROCESS

Biegler GmbH had no involvement with or knowledge of the HCPCS application that was submitted to establish a code for P-STIM or that such an application was under review. We only now understand that the HCPCS application has a signature line for the manufacturer's attestation. As Biegler GmbH maintains the manufacturer file related to K-letter K050123 "P-STIM", we assume that we should be the sole manufacturer with standing to sign such an application and attest to the truthfulness of the data submitted. Due to the fact that Biegler GmbH did not sign the HCPCS application of concern, we believe that the outlined process was not followed. Biegler GmbH stands prepared to submit an affidavit that we did not sign the HCPCS application and if a different organization did sign the HCPCS application, then we believe they are not qualified to do so as outlined above. In either case, we believe that the application is invalid, and should be immediately withdrawn from consideration and deleted from the May 29th agenda.

VALIDITY OF THE HCPCS APPLICATION – SALES DATA

Biegler GmbH understands after a thorough review of the HCPCS application and process that certain information in addition to our attestation is required that only we, as the manufacturer can be the source of. Sales volume for the three months prior to the application, for instance, is a required element of the application. Biegler GmbH maintains sales volume data for the P-STIM by country, including the United States, around the world. We have never provided U.S. sales volume data to Mr. Nageshwar to use in the HCPCS application. We believe that the three months of U.S. sales data required for a HCPCS application are invalid for this reason. Such U.S. sales data were not provided to any other party to use in connection with the submission of the HCPCS application for P-STIM on behalf of Biegler GmbH. This is an additional reason why we believe that the HCPCS application for P-STIM, whether the applicant is Mr. Nageshwar or someone else is invalid.

VALIDITY OF THE HCPCS APPLICATION – INTERNATIONAL EVALUATIONS OF "P-STIM"

Biegler GmbH is the manufacturer of P-STIM devices globally. As we maintain the FDA manufacturer file, we keep the manufacturer files that support the continued marketing of the product in countries around the world. It is our understanding that such information ("international evaluations of the product") is an additional required element of any HCPCS application. As we were not involved in the submission of this application, we did not provide the necessary "international evaluation of the product" data to the applicant, whether the applicant is, in fact, Mr. Nageshwar or another party. Again we believe that the necessary data were not provided by us to the process and we believe that the application is, thus, invalid whoever the applicant is.

USE OF THE TERM "P-STIM"

Biegler GmbH exclusively holds the trademark on the term "P-STIM" in the United States. It is our contention that when the applicant submitted the HCPCS application for "P-STIM" without involving the manufacturer, they were using our trademarked term, "P-STIM," in a manner in which they were not authorized to do by our company.

In summary, Biegler GmbH is aware of the late date of this letter in relation to the upcoming HCPCS public meeting on May 29th. With regard to Agenda Item #6, "P-STIM", we believe that the process outlined by CMS was not followed and that the data in the application are suspect. We believe that any one of the following issues could be grounds for withdrawal of the application as invalid:

1) The manufacturer of P-STIM was not involved in the application process as required.
2) The manufacturer of P-STIM (as determined by FDA regulatory files) did not sign the attestation (as required) and the application is presumed to be invalid.
3) Data in the application that can only be provided by the manufacturer (U.S. sales volume for three months prior to submission of the HCPCS application and a history of international assessments of the product) were not provided by Biegler GmbH, the manufacturer of P-STIM, and is presumed to be invalid.
4) "P-STIM" is a trademarked term controlled by Biegler GmbH, so when the applicant submitted this application, it did not have authority of the manufacturer to use this term in the application.
5) P-STIM is a trademarked term controlled by Biegler GmbH, and if an organization different from Biegler GmbH has identified itself as the "Manufacturer" of "P-STIM™" in the attestation section of the HCPCS application, it is misusing the term in doing so, as Biegler GmbH is the only company

authorized to identify companies as the manufacturer of P-STIM, and Biegler GmbH only recognizes one manufacturer of P-STIM which is Biegler GmbH.

6) Mr. Nageshwar has recently identified himself to Biegler GmbH as the applicant of the P-STIM HCPCS application. Biegler GmbH has not been involved in the application process.

Again I apologize for the disruption that this last minute letter will cause your process as you prepare for a successful meeting on May 29th.

In summary, Biegler GmbH respectfully requests that the HCPCS Application for P-STIM (Agenda Item #6 for the May 29th Public Meeting) be withdrawn and that the Agenda Item #6 be passed over and that this Agenda Item be set aside in its entirety without prejudice. It is our intention to pursue a HCPCS code at some future time when we are ready to do so, and it is important for us to do so in an environment that is not affected by an application that is invalid in many aspects. Thank you for your consideration.

Regards,

Biegler GmbH

Ingeborg Biegler
Managing Director